

SheppardMullin

Sheppard, Mullin, Richter & Hampton LLP
30 Rockefeller Plaza
New York, New York 10112-0015
212.653.8700 main
212.653.8701 fax
www.sheppardmullin.com

Paul W. Garrity
212.634.3057 direct
pgarrity@sheppardmullin.com

July 15, 2022

File Number: 0100-922638

VIA ECF

The Honorable Paul A. Engelmayer
United States District Court for the Southern
District of New York
Thurgood Marshall United States Courthouse
40 Foley Square
New York, NY 10007

Re: **Bayer Healthcare, LLC v. Perrigo Company, PLC; Civil Action No. 1:22-cv-05931**

Dear Judge Engelmayer:

This law firm represents defendant Perrigo Company, PLC (“Perrigo”) in the above-referenced matter. Pursuant to Your Honor’s Individual Practices Rule 4.B., we write to respectfully request that the Court issue an order permitting Perrigo to file under seal Exhibit E and Exhibit F to the Declaration of Valerie Gallagher, and citations thereto in Paragraphs 13 and 14 to the Declaration of Valerie Gallagher, in support of Perrigo’s Opposition to Bayer Healthcare, LLC’s (“Bayer”) Motion for Preliminary Injunction (collectively, the “Perrigo Submission”).

Perrigo will file redacted versions of the documents in Perrigo Submission on the public docket, and will provide the unredacted versions, with proposed redactions highlighted, to the Court and to all counsel of record in this matter.

I. Justification for Filing the Perrigo Submission Under Seal

In this Circuit, “[d]ocuments may be sealed if specific, on the record findings are made demonstrating that closure is essential to preserve higher values and is narrowly tailored to serve that interest.” *Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 119-24 (2d Cir. 2006). The Second Circuit employs a three-part analysis for determining whether documents filed with the Court may be maintained under seal. *See Lugosch*, 435 F.3d at 119; *Stern v. Cosby*, 529 F. Supp. 2d 417, 420 (S.D.N.Y. 2007) (citing *Lugosch*). The Court must first determine whether the documents at issue qualify as “judicial documents.” *Stern*, 529 F. Supp. 2d at 420. If the documents are indeed found to be “judicial documents,” the Court determines the weight of the common law presumption of public’s access to the judicial documents at issue. *Id.* Finally, after determining the weight of the presumption, the Court balances that presumption against the

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weight of the countervailing factors in favor of maintaining the documents under seal and preventing disclosure. *Id.* Perrigo's Submissions are judicial documents because they are filed in conjunction with an Opposition to Bayer's Motion for Preliminary Injunction. *Utica Mut. Ins. Co. v. Ina Reinsurance Co.*, No. 6:12-CV-194 (DNH/TWD), 2012 U.S. Dist. LEXIS 204381, at *12 (N.D.N.Y. June 12, 2012). Moreover, Because the Perrigo Submissions are filed in conjunction with an Opposition to Bayer's Motion for Preliminary Injunction, the presumption of public access is strong. *Id.* at *12. However, case law provides that studies included within FDA submissions are appropriate for sealing.

II. Interests Weigh In Favor of Sealing the Perrigo Submission.

A Court must balance the common law presumption of access against competing comparisons, including "the privacy interests of those resisting disclosure." *GoSmile, Inc. v. Levine*, 769 F. Supp. 2d 630, 649 (S.D.N.Y. 2011). Here, the interests resisting disclosure weigh heavily in favor of Perrigo.

"Commercially sensitive information related to the parties' confidential research and development plans, including information related to product performance testing, product specifications" may properly be filed under seal. *AngioDynamics, Inc. v. C.R. Bard, Inc.*, No. 1:17-cv-598 (BKS/CFH), 2022 U.S. Dist. LEXIS 120384, at *76 (N.D.N.Y. July 8, 2022). The documents Perrigo seeks to file under seal are internal Perrigo documents marked "Confidential," and the redactions Perrigo seek include commercially sensitive, non-public information related to the clinical and performance testing of Nasonex and research into the efficacy of Nasonex.

Moreover, these summary documents include studies and other information confidentially to the FDA for its new drug application (NDA) for Nasonex, and information submitted to the FDA related to safety and effectiveness may properly remain under seal. *See id.* (granting motion to seal 510(k) submission to the FDA and related information).

Exhibit E of the Gallagher Declaration is a summary of clinical studies and other information regarding the efficacy of Nasonex, which reveals confidential research and development into the Nasonex product and testing results regarding the performance of the product. Therefore, it should be sealed.

Exhibit F of the Gallagher Declaration, is a non-public reviewer's guide which summarizes the documents and studies Perrigo submitted to the FDA with its NDA submission for Nasonex. It contains confidential research and development information regarding Nasonex, and as such should be sealed.

Portions of the Gallagher Declaration which describe and quote portions of Exhibit E and Exhibit F must also be redacted and filed under seal because they reference and directly quote from the confidential research and development information therein.

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Given that the Perrigo Submission for sealing is only related to select portions of Perrigo's entire Opposition to Bayer's Motion for Preliminary Injunction filing, and the information the Perrigo seeks to seal relates to non-public, confidential, research and development findings, it is narrowly tailored. Perrigo respectfully requests that Your Honor permit the filing of the Perrigo Submission under seal.

We thank Your Honor for your time and consideration of the this matter.


Respectfully submitted,

/s/ Paul W. Garrity

Paul W. Garrity
for SHEPPARD, MULLIN, RICHTER & HAMPTON LLP

SMRH:4868-7354-5001.4

Granted. SO ORDERED.



PAUL A. ENGELMAYER
United States District Judge
7/20/22